IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

CLASSEN IMMUNOTHERAPIES, INC.	*	
Plaintiff,	*	
v.	*	CIVIL NO.: WDQ-04-3521
KING PHARMACEUTICALS, INC. *et al.*,	*	
Defendants.	*	

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MEMORANDUM OPINION

Classen Immunotherapies, Inc. ("Classen") sued Elan Pharmaceuticals, Inc. ("Elan") for infringement of two patents. ECF No. 1 at 1-2. The litigation was stayed while the United States Patent and Trademark Office ("PTO") completed a reexamination of the patents. ECF Nos. 179 at 1, 204 at 1. Pending is Classen's motion to lift the stay on this litigation, dismiss claims based on an invalidated patent, and vacate the Court's prior grant of summary judgment to Elan. ECF No. 204 at 2-3. No hearing is necessary. Local Rule 105.6 (D. Md. 2012). For the following reasons, Classen's motion will be granted in part and denied in part.

I. Background[1]

Classen is a Maryland corporation that developed and patented methods for identifying and commercializing new uses of existing drugs. ECF No. 1 at 1. Classen is the holder of Patent 6,584,472 B2, "Method, System and Article for Creating and Managing Proprietary Product Data" (the "472 patent"). *Id.* It was also previously the holder of Patent 6,219,674 B1, "System for Creating and Managing Proprietary Product Data" (the "674 patent"). *See id.* However, upon reexamination, the PTO determined that the 674 patent is invalid. ECF Nos. 179 at 1, 204 at 1.

Elan is an Irish pharmaceutical company. ECF No. 1 at 2. Until 2003, Elan produced Skelaxin, a muscle relaxant. ECF Nos. 1 at 3, 123-3 at 2. In 2001, Elan learned of a study, conducted by a generic drug manufacturer, which indicated that Skelaxin's rate of absorption differed inside and outside the body. *See* ECF No. 123-5 at 1-2. Elan conducted its own study in July 2001, and found that food had a significant effect on Skelaxin's bioavailability. *See id.* Based on these findings, Elan submitted a Citizen Petition to the Food and Drug Administration

[1] The facts are taken from the complaint, ECF No. 1; the amended answer, ECF No. 119; Elan's motion for summary judgment, ECF No. 123, and supporting exhibits; Classen's opposition to Elan's motion, ECF No. 138 (sealed), and supporting exhibits; Classen's motion to vacate, ECF No. 204, and supporting exhibits; and Elan's opposition to Classen's motion to vacate, ECF No. 205, and supporting exhibits.

("FDA") requesting that the FDA require drug manufacturers seeking approval of generic forms of Skelaxin to submit fed and fasted studies in Abbreviated New Drug Applications ("ANDA"). *See id.*; ECF No. 123-1 at 3. Elan also submitted a labeling supplement to its New Drug Application ("NDA") for Skelaxin that included the results of the study. ECF No. 123-7.

The FDA granted Elan's request for a requirement of fed and fasted studies for all generic Skelaxin ANDAs and approved Elan's amendments to the Skelaxin product label. ECF No. 123-6. Elan was also ultimately granted patent numbers 6,407,128 and 6,683,102 on the relabeled Skelaxin. ECF No. 123-3 at 2.

Classen alleged that Elan infringed the 472 and 674 patents when it: 1) studied the effect of food on the bioavailability of Skelaxin; 2) used the study data to identify a new use of the drug; and 3) commercialized the new use. ECF No. 123-8 at 5-6. Elan counterclaimed, arguing that Elan did not infringe Classen's patents, the patents are unenforceable and invalid, and that Classen defamed Elan, invaded its privacy and damaged its business by issuing a false press statement and by claiming that Elan and Classen had an ongoing business relationship. ECF No. 119 at 7-12.

On August 17, 2006, the Court granted Elan summary judgment on Classen's infringement claims. ECF No. 167. The Court held that Elan's use of Classen's patent process was "reasonably

related to the submission of information under the FDCA,"[2] and was accordingly protected by a statutory safe harbor, 35 U.S.C. § 271(e)(1). ECF No. 166 at 5. The Court also denied Classen's motion for partial summary judgment on Elan's counterclaims. *Id.* at 6-9.

On December 14, 2006, the Court administratively closed the case pending the PTO's reexamination of the 674 and 472 patents. ECF Nos. 179 at 1, 204 at 1. Following the completion of the examination, on December 19, 2012, Classen moved to reopen the case, lift the stay,[3] vacate the Court's grant of summary judgment to Elan,[4] and dismiss all claims and counterclaims based on the now invalid 674 patent. ECF No. 204 at 2. On January 7, 2013, Elan opposed the motion. ECF No. 205. On January 26, 2013, Classen replied. ECF No. 207.

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[2] "FDCA" refers to the Food, Drug, and Cosmetic Act. Elan submitted its supplemental NDA ("sNDA") pursuant to § 505(b) of the Act (35 U.S.C. § 355(b)). ECF No. 123-7 at 1. The Citizen Petition was submitted under FDA Rule 21 C.F.R. § 10.30. ECF No. 123-5 at 1.

[3] Because this case was stayed pending the PTO's reexamination of the patents, *see* ECF No. 179, and this review is now complete, ECF No. 204 at 1-2, the motion to lift the stay will be granted.

[4] Classen asserts that the Federal Circuit's recent decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, warrants reconsideration of the Court's decision. ECF No. 204 at 2-3.

II. Analysis

A. Motion to Dismiss Claims

Classen requests dismissal of all patent infringement claims, affirmative defenses, and counterclaims based on the 674 patent. ECF No. 204 at 2. Elan does not oppose this motion, except as to its 674 patent unenforceability counterclaim. ECF No. 205 at 15-16.

Elan's amended answer's requested relief for its counterclaims includes an award of costs and attorneys' fees under 35 U.S.C. § 285. This provision authorizes an award of attorney fees in "exceptional cases." § 285. Exceptional cases may include those in which the patent holder has engaged in inequitable conduct in obtaining the patent. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). Elan asserts that the unenforceability counterclaim "is a component of Elan's motion for exceptional case and attorneys' fees," if "Elan is determined to be the prevailing party." ECF No. 205 at 15. Elan also contends that "a finding of unenforceability of the '674 patent may be used to render the '472 patent unenforceable based on infectious unenforceability principles." *Id.* at 16.

In *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1242-43 (Fed. Cir. 2008), the Federal Circuit held that a district court retains jurisdiction over a patent

unenforceability claim after the patent is no longer in suit in order to determine whether a patent holder engaged in "inequitable conduct" and thus may be liable to the prevailing party for attorneys' fees. *Cf. Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1348 (Fed. Cir. 2005) ("[A] counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement that are not disposed of by a decision of non-infringement.").

The *Monsanto* court also noted that it had previously held that "'because inequitable conduct with respect to one or more patents in a family can infect related applications,'" there is "'no abuse of discretion'" when a district court retains jurisdiction over unenforceability claims as to withdrawn patents. *See* 514 F.3d at 1243 (*quoting Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007)); *cf. Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990) ("[A] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application."). Accordingly, this Court retains jurisdiction over Elan's 674 patent unenforceability counterclaim, despite the patent's invalidity.

The Court has already granted Elan summary judgment on all of Classen's infringement claims, *see* ECF Nos. 123, 166-67, 173-1 at 9, and will not reconsider that holding, *see infra* Section

II.B. Accordingly, the Court will deny Classen's motion to dismiss its infringement claims related to the 674 patent as moot. The Court will grant Classen's motion to dismiss all defenses and counterclaims related to the 674 patent, except Elan's unenforceability counterclaim.

B. Motion to Vacate

Although Classen does not caption its motion as a motion to reconsider, or identify the Federal Rule of Civil Procedure it brings this motion under, Classen asserts that the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, "warrants the reconsideration" of the Court's grant of summary judgment to Elan. ECF No. 204 at 2.

A party may move to alter or amend a judgment under Rule 59(e), or for relief from a judgment or order under Rule 60(b). *See* Fed. R. Civ. P. 59(e) & 60(b). A motion to alter or amend filed within 28 days of the judgment is analyzed under Rule 59(e); if the motion is filed later, Rule 60(b) controls. *See* Rule 59(e); *MLC Auto., LLC v. Town of S. Pines*, 532 F.3d 269, 280 (4th Cir. 2008); *In re Burnley*, 988 F.2d 1, 2-3 (4th Cir. 1992). Because the Plaintiff's motion was filed more than 28 days following the summary judgment order,[5] it will be analyzed under Rule 60(b).

[5] Classen's motion to reconsider the Court's August 17, 2006 order granting summary judgment was filed on December 19, 2012.

Rule 60(b) permits the Court to amend a final judgment, order, or proceeding because of: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence; (3) fraud, misrepresentation, or misconduct by an opposing party; (4) a void judgment; (5) satisfaction, release, or discharge of a judgment; or (6) any other reason justifying relief. Rule 60(b). Relief on the first three grounds must be requested "no more than a year after the entry of the judgment." Rule 60(b)(c)(1).

A Rule 60(b) motion is appropriate to raise a significant change in the law or facts, or when "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *See Above the Belt, Inc. v. Mel Bohannan Roofing, Inc.*, 99 F.R.D. 99, 101 (E.D. Va. 1983). "A motion to reconsider is inappropriate where it merely seeks to re-debate the merits of a particular motion," *Remediation Products, Inc. v. Adventus Americas, Inc.*, 3:07CV153-RJC-DCK, 2010 WL 2572555, at *1 (W.D.N.C. June 22, 2010), or merely requests that the district court change its

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ECF Nos. 166-67, 204. Although the case has been stayed for almost seven years, more than 28 days passed between the disputed order of August 17, 2006 and the implementation of the stay on December 14, 2006. *See* ECF No. 179.

mind, *United States v. Williams*, 674 F.2d 310, 313 (4th Cir. 1982).[6]

1. Safe Harbor Applicability

Classen contends that the Court's holding that Elan was protected by the § 271(e)(1) safe harbor is no longer valid in light of the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed Cir. 2011) *cert. denied*, 133 S. Ct. 973, 184 L. Ed. 2d 751 (2013). *See* ECF No. 204-1 at 13-14, 16. Elan asserts that Classen relies on a distorted interpretation of *Classen*, and that the Federal Circuit's decision in *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) *cert. denied*, 133 S. Ct. 2854 (2013), confirms that Elan was protected by the safe harbor. *See* ECF No. 205 at 8-9.

Section 271(e)(1) provides that it is not patent infringement "to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." This Court previously held

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[6] *See also Pritchard v. Wal Mart Stores, Inc.*, 3 F. App'x 52, 53 (4th Cir. 2001); *Medlock v. Rumsfeld*, 336 F. Supp. 2d 452, 470 (D. Md. 2002); *Erskine v. Bd. of Educ.*, 207 F. Supp. 2d 407, 408 (D. Md. 2002).

that Elan had not infringed Classen's patents, because it was covered by this safe harbor:

> Even assuming that Elan employed Classen's patented process when it studied Skelaxin's bioavailability problem and used the results to repatent the drug, the results of the 2001 study were submitted to the FDA in Elan's Citizen Petition and labeling supplement to its NDA. Therefore, Elan's use of the patented process was reasonably related to the submission of information under the FDCA and so is protected under § 271(e)(1).

ECF No. 166 at 5.

In 2011, the Federal Circuit considered the scope of § 271(e)(1) in a suit brought by Classen against Biogen IDEC ("Biogen") and GlaxoSmithKline ("GSK") claiming infringement of three of Classen's other patents. *See Classen*, 659 F.3d at 1060, 1070. Biogen and GSK participated in studies "to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk." *See id.* at 1070. (internal quotation marks and punctuation omitted). They submitted the results of these studies to the FDA, because the FDA requires annual progress reports of any post-approval studies that produce "adverse information." *See id.* at 1084 (Moore, dissenting) (*citing* 21 C.F.R. §§ 600.80, 601.70). The Court held that the safe harbor "does not apply to information that may be routinely reported to the FDA, long after marketing

approval has been obtained." *Id.* at 1071. The Court also emphasized that the purpose of the safe harbor is "to expedite development of information for regulatory approval of generic counterparts of patented products." *Id.*

In 2012, the Federal Circuit again considered the scope of § 271(e)(1) in *Momenta*. Momenta, already a manufacturer of a generic version of enoxaparin, sued another drug manufacturer, Amphastar, which sought to bring its own generic version of enoxaparin to market. *See Momenta*, 686 F.3d at 1351. Momenta claimed that Amphastar used one of Momenta's patented methods to test its drug for the presence of a particular non-naturally occurring sugar. *Id.* at 1352. Amphastar asserted that its testing was covered by § 271(e)(1), because it was required by the FDA "as a condition for the post-FDA approval sale of enoxaparin." *Id.* at 1352-53. The Court emphasized that the statutory language of the safe harbor mandated a broad interpretation of its coverage, noting that the Supreme Court "explicitly rejected the notion that § 271(e)(1) was limited 'to the activities necessary to seek approval of a generic drug.'" *See id.* at 1356 (*quoting Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206, 125 S. Ct. 2372, 2383, 162 L. Ed. 2d 160 (2005)). If the alleged infringer "'has a reasonable basis for believing' that use of the patented invention might yield information that 'would be appropriate to include in a

submission to the FDA, that use is reasonably related to the development and submission of information under . . . Federal law.'" *Id.* (*quoting Merck KGaA*, 545 U.S. at 207) (internal quotation marks omitted). Consistent with this broad view, the Court rejected any "artificial" distinction in the safe harbor's coverage between pre-FDA approval and post-approval activities. *Id.* at 1358-59.

The Court held that Amphastar's post-approval studies were covered by the safe harbor, because they were "reasonably related to the development and submission of information" under the FDCA. *Id.* at 1358-59. The Court distinguished *Classen*, which involved "routine[]" studies that "did not facilitate marketing a generic drug by 'expedit[ing] development of information for regulatory approval,'" from *Momenta* which involved information "necessary both to the continued approval of the ANDA and to the ability to market the generic drug." *See id.* at 1358. Amphastar's studies were far from "routine," because they were required to maintain FDA approval. *Id.*

Here, the results of Elan's study were submitted to the FDA, pursuant to 21 C.F.R. § 10.30, in a Citizen's Petition which requested that "the Commissioner of Food and Drugs [] require an acceptable *in vivo* bioequivalence study conducted under fasting and fed conditions as a requirement for approval of an abbreviated new drug application (ANDA) for a generic version of

Skelaxin." ECF No. 123-5 at 1. In addition, Elan included the results of the study in its sNDA to update Skelaxin's label to account for the study's findings. *See* ECF No. 123-7 at 1. As this Court held previously, these activities are "reasonably related to the submission of information under the FDCA." ECF No. 166 at 5. That these activities occurred after Skelaxin's FDA approval does not automatically remove them from the safe harbor. *See Momenta*, 686 F.3d at 1358-59.

Although, unlike the defendants in *Momenta*, Elan was not required to submit the study results to the FDA, *Momenta* did not hold that only information that the FDA "required" could be considered not "routine" under *Classen*. *See, e.g., id.* at 1356 (safe harbor not limited to activities required to obtain approval of a generic drug). Instead, *Momenta* emphasized that the safe harbor should be interpreted expansively. *See, e.g., id.* at 1356 ("'Under a federal law' extends beyond just the 'most barebones information' required by the FDA, and instead encompasses all 'materials the FDA demands in the regulatory process.'" (*quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1683-84, 182 L. Ed. 2d 678 (2012)). Unlike the activities of the *Classen* defendants, which involved simply reporting their studies' results to the FDA,[7] Elan's allegedly

[7] *See Classen Immunotherapies, Inc. v. Biogen IDEC*, 381 F. Supp. 2d 452, 455 (D. Md. 2005) (GSK and Biogen argue that their study

infringing study prompted its request for changes to the FDA approval process for generic versions of Skelaxin. *See* ECF No. 123-5 at 2. In other words, Elan's study "expedit[ed] development of information for regulatory approval" of a generic version of Skelaxin, an activity that the *Classen* court suggested was directly related to the purpose of the safe harbor, and, thus, presumably not "routine."[8] *See Classen*, 659 F.3d at 1070; *see also Momenta*, 686 F.3d at 1358 (*Classen* holding based in part on fact that defendants did not "facilitate marketing a generic drug"). In addition, submission of the study results to the FDA was necessary to update the label to include the findings of that study,[9] and thus according to *Momenta*, was not routine. *See Momenta*, 686 F.3d at 1358. Accordingly, because Elan's study resulted in submissions to the FDA that were not routine and were "reasonably related to the

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falls under the safe harbor, because the FDA "collects vaccine data from vaccine manufacturers after their vaccines have been approved").

[8] Elan did not market a generic version of the drug, but the study altered the approval process for generic versions of Skelaxin produced by other manufacturers. *See* ECF Nos. 57-2 at 6, 123-6 at 1. *Classen* does not hold that the safe harbor is limited to actual generic manufacturers, *see, e.g.*, *Classen*, 659 F.3d at 1070, and *Momenta* suggests that the only limits on the safe harbor is the requirement that the submission not be routine under *Classen* and that it be "pursuant to a federal law regulating the 'manufacture, use, or sale of drugs or veterinary biological products,'" *see Momenta*, 686 F.3d at 1357-59.

[9] *See* ECF Nos. 123-1 at 4, 7 n.3; 123-7 at 1-2.

submission of information under the FDCA," *see* ECF No. 166 at 5, it was within the safe harbor after *Classen* and *Momenta*. Classen's motion to reconsider the Court's grant of summary judgment to Elan will be denied.

2. Other Arguments

Other than Classen's arguments that the *Classen* and *Momenta* decisions require this Court to vacate its previous grant of summary judgment to Elan, Classen makes no new arguments in its motion to reconsider. Instead, Classen simply resubmits the arguments it made in opposition to Elan's motion for summary judgment. *Compare* ECF No. 138 at 5-28, *with* ECF No. 204-1 at 17-29. The Court will not grant a motion to reconsider based on arguments it has considered and rejected.[10] Accordingly, the motion to reconsider will be denied.

[10] *See Pritchard*, 3 F. App'x at 53 ("When the motion raises no new arguments, but merely requests the district court to reconsider a legal issue or to 'change its mind,' relief is not authorized.").

III. Conclusion

For the reasons stated above, Classen's motion will be granted in part and denied in part--the stay on this case will be lifted.

10/31/13
Date

William D. Quarles, Jr.
United States District Judge